PROTOCOL 1

Genetic Epidemiology of Prostate Cancer in Africa
Study Coordination (Steps)

The aim of this US National Institutes of Health (NIH) research study is to enroll male cases with prostate cancer and male controls through hospital clinics from six recruitment sites in Africa. Detailed medical information will be collected and a biospecimen obtained for DNA extraction. When sufficient samples have been collected a genome wide association study will be undertaken to discover new and validate known prostate cancer loci in African men.

This document serves as a resource for the Project Manager (PM) as h/she undertakes the processes described in the **U01-CA184374 Study Overview** document and should be used in conjunction with the Protocols and Forms described below. At any step prior to consenting in the study, and during participation, the subject may decide to continue or discontinue. It is also possible that the subject may not be able to participate in all steps of the study even though he consented to the process and the PM will document all information about step completion on the **Enrollment Checklist Form for Cases and Controls**. This information will be entered by the PM into the research DatStat database.

Step 1: Inclusion/Exclusion Criteria

Prior to, and upon meeting with the potential case, or control, in the clinic, the project manager should determine that he meets ALL inclusion criteria and does not meet ANY exclusion criteria following the information provided in **Protocol 1** (Cases) and **Protocol 2** (Controls).

↓ **Interested**

Step 2: Eligibility Status

If all inclusion criteria are met the PM should sit with the potential case/control and complete **Form 1-Case Eligibility Form** or **Form 2-Control Eligibility Form**. He/she should communicate using simple language, overview the main criteria for the study and complete the eligibility form(s). All **Eligible** boxes of the form must be checked in order to be able to participate in this research study.

It is during completion of the eligibility form that the PM will determine whether the subject appears cognitively able to participate in the study. If the subject does not appear capable of answering all questions in full, or if the PM has any doubt as to his ability to participate, h/she should deliver **Form 3-Cognitive Assessment**. *Please note: Form 3 should only be delivered to those who appear to be unable to fully understand the study requirements and who may be unable to fully understand the consent process*. Upon completion of the cognitive assessment the PM will finalize eligibility status and determine whether the subject is eligible to be included in the study, is interested in participation, or does not want to proceed. Information from these forms will subsequently be entered by the PM into the DatStat database.

↓ **Eligible**
Interested

Step 3: Informed Consent

Informed consent is used to convey to the subject the risks and benefits of participating in the research study. The PM should take the time to review the form in detail answering any questions that may arise and obtain a signature from the subject to indicate he consents to the study as well as signing as the investigator/associate who consented the participant into the study. **Form 4. Consent** will serve as written documentation of the discussion and provides assurance that the subject is fully informed about the study goals, requirements and benefits. The PM should ensure that the consent form is presented to the subject in a language they understand. Upon completion of the consent process, the study instruments will be administered. The overall time that will be spent participating in all parts of the study should be relayed to the subject so they can make an informed decision as to whether to continue or not. The PM will subsequently enter into the DatStat database information regarding signed consent having been obtained by the subject and choice regarding use of specimens for future studies.

Step 4: Cover sheet

Form 5. Cover sheet contains sensitive identifiable information and will be maintained at the local center only. The PM will enter demographic data from the subject on the form as Please see **Protocol 4. Participant identifier assignment** for details on assigning, and creating labels with a unique identifier for each subject. Information from this form will subsequently be entered by the PM into the DatStat database.

Step 5: Questionnaire & Body mass index

The PM will review and complete the contents of **Form 6. Questionnaire Cases and Controls** with the subject. (Please note that this questionnaire is site specific: Section A questions 2 and 6 are specific to each center). It should take between 30-45 minutes to deliver this survey. The PM will also obtain the height, weight, waist circumference and hip circumference on the subject using **Form 7. Body Mass Index**. Information from these forms will subsequently be entered by the PM into the DatStat database.

Step 6: Medical record abstraction

This step can take place at any point after the subject has consented into the study. The PM will abstract the information from the subject's medical record and document details on **Form 8. Medical record abstraction cases** or **Form 9. Medical record abstraction controls**. This information will subsequently be entered by the PM into the DatStat database.

Step 7: Biospecimen sampling

The PM will take the subject to the phlebotomist/nurse who will be drawing blood for the study and should complete **Form 10. Biospecimen Collection Form** and follow **Protocol 5. Blood sampling.** The minimum

requirement for this study is to collect at least 10 cc of blood into purple capped (EDTA) tube(s) for DNA extraction. Ideally 20cc should be obtained. It is optional to also collect blood in red capped tube(s) for serum. The specimens obtained will be labeled using the same unique identifier that was assigned for the subject during Step 4 above and will affix a printed label onto each sample collected. Saliva/Mouthwash/Buccal swabs should ONLY be obtained from the subject if it is not possible to obtain a blood sample and should be obtained following **Protocol 6. Saliva sampling**, **Protocol 7. Mouthwash sampling** and **Protocol 8. Buccal swab sampling.** Blood samples and buccal swabs should be refrigerated prior to DNA extraction and ideally should be processed within 48 hours. If blood cannot not be processed within 48 hours IT MUST be frozen at -80°C prior to DNA extraction. Saliva samples and mouthwash may be stored at room temperature prior to DNA extraction. DNA extraction should ideally take place within 24 hours of sampling in order to maximize DNA yields.

Step 8: DNA metrics

DNA should be extracted following **Protocol 9. DNA extraction-Qiagen QIAamp DNA kit,** cleaned up if necessary following **Protocol 10 Genomic DNA Cleanup** and DNA plated onto Biomatrica DNA stable plate following **Protocol 11. DNA stable plate**. **Form 11. DNA Metrics** should be completed to provide a detailed record of DNA volume, concentration, QC metrics and storage location. This information will in future be entered by the PM to the DatStat database.

Step 9: DNA shipment to CPGR

DNA will be shipped to CPGR for future genotyping and analysis. A pilot study is being conducted and study centers will follow Protocol **Protocol 12. CPGR DNA Stable plate validation pilot** in order to prepare samples for shipment and complete **Form 12. Acceptance Form_StablePlate validation** and **Form 13. Sample Submission and Sample Layout form**.

Step 10: Data access

In future the Data Access Coordination Committee will review request from Investigators wishing to perform analyses on data obtained from this research study who should complete their analysis concept on **Form 14. Data access**.